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**FACTORS INFLUENCING REVISION RISK FOLLOWING 15,740 SINGLE-BRAND  
HYBRID HIP REPLACEMENTS**  
**A Retrospective Cohort Study from a National Joint Registry**

**Simon S Jameson, MRCS<sup>1</sup>**

**James Mason, DPhil MSc BSc (Hons)<sup>2</sup>**

**Paul Baker, MSc FRCS (Tr&Orth)<sup>1</sup>**

**Prithee Jettoo, MRCS<sup>3</sup>**

**David J Deehan, MD MSc FRCS (Tr&Orth)<sup>4</sup>**

**Mike R Reed, MD FRCS (Tr&Orth)<sup>5</sup>**

*From:*

***The National Joint Registry for England and Wales***

<sup>1</sup>Research Fellow

<sup>2</sup>Professor of Health Economics

***School of Medicine and Health, Durham University, Queen's Campus, University  
Boulevard, Stockton-on-Tees, TS17 6BH, UK***

***Northern Deanery Trauma & Orthopaedic Training Scheme, Waterfront 4, Goldcrest Way,  
Newcastle, NE15 8NY, UK***

<sup>3</sup>Specialty Registrar

<sup>4</sup>Consultant Orthopaedic Surgeon

***Newcastle Hospitals NHS Foundation Trust, Freeman Road, High Heaton, Newcastle  
upon Tyne, NE7 7DN, UK***

<sup>5</sup>Consultant Orthopaedic Surgeon

***Northumbria Healthcare NHS Foundation Trust, Woodhorn Lane, Ashington,  
Northumberland, NE63 9JJ, UK***

*Corresponding Author:*

**Simon Jameson**

2 Ashville Avenue, Eaglescliffe, Stockton-on-Tees, TS16 9AX, UK

Tel: +44 7812603112 / Email: [simonjameson@doctors.org.uk](mailto:simonjameson@doctors.org.uk)

## Abstract

*This retrospective cohort study of a National Joint Registry data examines survival time to revision following the commonest brand of primary hybrid THR, exploring risk factors independently associated with failure. Overall 5-year revision was 1.56%. In the final adjusted model, revision risk was significantly higher with standard polyethylene (PE) liners (metal-on-PE: hazard ratio (HR)=2.52,  $p=0.005$ , ceramic-on-PE:  $HR=2.99$ ,  $p=0.025$ ) when compared to metal-on-highly-cross-linked (XL) PE. Risk of revision with ceramic-on-ceramic bearings was borderline significant ( $HR=1.86$ ,  $p=0.061$ ). A significant interaction between age and acetabular shell type (solid or multi-hole) was found ( $p=0.022$ ), suggesting that solid shells performed significantly better in younger patients. In summary, we found there were significant differences in implant failure between different bearing surfaces and shell types after adjusting for a range of covariates.*

Running title: Factors influencing revision risk following 15,740 single-brand hybrid hip replacements

Key words: hybrid total hip replacement, bearings, revision, acetabular shell

## **Introduction**

Primary cemented total hip replacement (THR) has good medium- to long-term implant survival across national joint registries and meta-analyses globally (1-8). However, for younger patients with higher demands, a cemented polyethylene cup may fail at a greater rate, and may not provide sufficient longevity. Hybrid THRs, where a cemented stem is coupled with a cementless cup, may be an attractive option in these patients. Cementless modular acetabular components allow the use of a range of bearing surfaces in combination with larger head sizes. When these implants were examined in patients under 70 years in England and Wales, the National Joint Registry (NJR) found that hybrid THRs had equivalent 5-year revision rates when compared to cemented implants, and superior revision rates when compared to cementless implants in females (7). In addition, Australian registry data for patients aged 50 to 64 years has demonstrated superior results with hybrid implants compared to both cemented and cementless implants (8). In 2010, 16% of 68 907 THRs in England and Wales were hybrid procedures (7).

National registry data allows independent analyses of large volumes of procedures over an entire population. However, there are limitations to these analyses. Despite the numerous implant options and materials used, many registries analyse implants using simple discriminators, such as fixation type, when in reality no two brands of implants are alike, and assumptions of similarity may be misplaced.

The aim of this study was to explore factors that may affect the risk of revision in a national cohort of patients undergoing a single combination of hybrid THR, using data from the NJR (9). Each brand of implant has a range of parameters that may influence the risk of failure over time. These parameters are not all comparable across brands e.g. acetabular shell type.

Thus, to explore the determinants of failure it was appropriate to limit the analysis to the most common hybrid brand combination recorded on the NJR (7).

## **Materials and methods**

### ***Design***

A retrospective cohort study was conducted to assess patient level NJR data for survival time to revision for the commonest brand of primary hybrid THR.

### ***Data***

The NJR has assimilated data on patients, surgeons and implants performed in both the private and public sector (National Health Service, NHS) in England and Wales since 2003. According to the NJR 8<sup>th</sup> Annual Report, the commonest brand combination of hybrid THR used in England and Wales since 2003 features the Stryker Exeter V40 hip and Trident socket (Stryker Orthopaedics, Mahwah, New Jersey, United States), accounting for 33.0% of all hybrid THRs (18 358 of 55 551) (7). The Exeter V40 femoral stem is a polished, double tapered, collarless stainless steel design with a ‘V40’ taper and a hollow distal centraliser to allow subsidence for compressive loading throughout the cement mantle. It is available in a range of stem widths (0 to 5), offsets (30mm to 56mm) and lengths (short: 104 to 134mm, standard: 158mm, and ‘long stem’ options: 200mm to 260mm). The Trident Acetabular System is an uncemented modular cup manufactured from hydroxyapatite (HA) coated porous titanium (non-HA coated Trident cups are not available in the United Kingdom). Liner options include standard polyethylene (PE), highly cross-linked (XL) PE (first generation: ‘Crossfire’, and second generation: ‘X3’), alumina ceramic, and constrained. The shells are available as a press-fit no-hole (‘Solid-back’) type, or in multi-hole (‘5-hole’, ‘Cluster-hole (3-hole)’ and ‘Multi-hole’) form, allowing supplementary fixation with acetabular screws. Two types of shell geometry are manufactured: ‘Hemispherical’ and ‘Peripheral self-locking’ (PSL, or rim-fitting). Femoral heads are available in stainless steel (‘Orthinox’: 22, 26, 28, 30, 32, and 36mm), cobalt-chrome (‘Vitallium’: 28, 32, 36, 40, and

44mm) and ceramic ('Alumina' 28, 32, and 36mm). Three brands of cement have been used with these components: 'Palacos' (three manufacturers: Heraeus Holding GmbH, Hanau, Germany; Schering-Plough Corporation, Kenilworth, New Jersey, USA; Biomet Inc., Warsaw, Indiana, USA), 'CMW' (DePuy Orthopaedics Inc., Warsaw, Indiana, USA) and 'Simplex' (Stryker Corporation, Kalamazoo, Michigan, USA). Palacos and CMW are available as high and low viscosity, and all brands have plain or antibiotic impregnated versions. Data were extracted for all Exeter/Trident THRs performed and submitted to the NJR until 31<sup>st</sup> December 2010 with the primary diagnosis of osteoarthritis (OA). As several options were used rarely, these were excluded from analyses. A summary of inclusion criteria is shown in Figure 1.

Covariate categories thought to have an influence on revision risk were patient age at time of procedure, gender, co-morbidity score, body mass index (BMI), stem size, bearing surface material and head size (10-12). American Society of Anaesthesiology (ASA) grade was used as a surrogate for co-morbidity. We also examined the influence of head offset, acetabular shell type and primary surgeon characteristics. Covariates used are summarised in Table 1.

For an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure), a complete record of the revision procedure (including side of operation) must be linked to the original index procedure by matching the unique patient identifier. A number of causes of revision can be recorded for each operation; these were interpreted hierarchically for infection and peri-prosthetic fracture, pre-selecting in that order. Pain was only taken as the primary cause when no other reason was provided.

### ***Statistical analysis***

Continuous and discrete continuous covariates (age, head offset, consultant volume) were analysed as categorical data (informed by spread of the data) because of the greater clinical relevance when making group comparisons. Preliminary analysis of age as a continuous variable is also reported. To explore the influence of covariates the most common category was generally used as the baseline case: for example, 32mm heads were used as the baseline against which all other head sizes were compared. Exceptions to this were age (where the youngest group was used as the baseline), consultant volume (where the highest volume group was used) and bearing (where the type most commonly used in 2010 was used).

A revision procedure was considered to be a ‘failure event’, where the time between the index procedure and revision was the measure of joint survival. Survival times for patients who had not undergone revision were censored at the study census date (31<sup>st</sup> December 2010). Kaplan-Meier survival charts were generated to display visual differences in unadjusted covariates. The log-rank (Mantel-Cox) test was used to perform paired comparisons between each of the covariates using the pair-wise over strata method. Covariate categories with significant influences are presented, with life tables to describe numbers within each covariate category entering each year of the study.

Cox proportional hazard models were used to assess the extent to which the timing of revision could be explained in terms of the measured patient, surgeon and implant covariates. Results are presented as Hazard ratios (HRs) with 95% confidence intervals (CI): ratios greater than one indicate that risk is higher when compared with the reference covariate category. Covariates fitting models with  $p < 0.05$  were considered significant influences.



Life tables were produced to report unadjusted one-, three-, and five-year revision rates (with 95% CIs estimated using the normal approximation) for each shell type and bearing in patients  $\leq 75$  years. Survival was not reported if number entering the first year was less than 500, or number entering any subsequent year was less than 5% of the original number entering in that group.

## **Results**

Of 15 740 primary procedures, the majority were performed in females (9573, 60.8%), with ASA  $\leq 2$  (13 693, 87.0%) and 75 years of age or less (11 764, 74.7%); the mean age at implantation was 68 years old. There were 6641 (42.2%) procedures with complete BMI data; of the procedures with data, the majority were less than 30kg/m<sup>2</sup> (4638, 69.8%). The most commonly used stem was 44mm offset (8627, 54.8%) and taper sizes  $\leq 2$  (14 255, 90.6%) accounted for the majority. A standard neck offset (63.4%, 9986) and a 32mm diameter (45.4%, 7153) were the most commonly used heads. The commonest cup design was a PSL multi-hole (10 497, 66.7%) and only 33.3% (5243) relied on press-fit fixation with a solid-back shell. Over the entire study, the commonest bearing was ceramic-on-ceramic (CoC, 6144, 39.0%). However, during 2010 this was metal-on-XLPE (MoXLPE). Palacos high viscosity antibiotic impregnated (52.5%, 8264) was most commonly used to cement the stem. The procedure was performed through a posterior approach in 67.5% of cases (10 620). In most cases the consultant performed the procedure (12 886, 81.9%). Medium- or high-volume Exeter/Trident hybrid arthroplasty surgeons ( $\geq 51$  cases over study period) accounted for 70.8% (11 147) of procedures. Patients were under the care of 575 different consultants in 239 different surgical units. Demographics are shown in Table 2 and bearing use by year in Table 3.

## ***Reasons for revision***

One hundred and forty-one patients had undergone a revision procedure by the census date. The most common reason was infection (38 revisions, 27.0% of all revisions). Reason for revision was determined to be dislocation in 36 cases (25.5%), followed by aseptic component loosening/lysis (33, 23.4%), malalignment (18, 12.8%) and peri-prosthetic

fracture (17, 12.1%). Revision for dissociation of liner occurred in seven patients (5.0%), five of which were ceramic liners (3.5%). Revision data are summarised in Table 4.

### ***Associations with implant revision***

In simple (univariable) regression analysis, age ( $p=0.033$ ), bearing ( $p=0.050$ , Figure 2), shell type ( $p=0.024$ , Figure 3), and surgical approach ( $p=0.036$ ) influenced implant revision risk (Table 5). Although bearing category was on the threshold of significance, several individual bearings had  $p<0.05$ . Brand of cement, shell geometry and type of femoral head metal (stainless steel or cobalt-chrome) were not found to be significant influences for survival: these covariates were therefore merged into common categories. First- ('Crossfire') and second-generation ('X3') XLPE liners were combined into one group, as the 'Crossfire' liner was used rarely.

After risk adjustment, procedures performed using standard PE liners (metal-on-PE bearings: HR=2.64, 95% CI 1.39 to 4.99,  $p=0.003$ , ceramic-on-PE: HR=3.07, 95% CI 1.18 to 8.00,  $p=0.022$ ) and CoC bearings (HR=1.93, 95% CI 1.00 to 3.69,  $p=0.049$ ) were associated with significantly higher revision rates when compared with procedures using a MoXLPE bearing. Procedures employing multi-hole acetabular shells (HR=1.70, 95% CI 1.16 to 2.48,  $p=0.006$ ) had a greater risk of revision compared with solid-back shells. Older patients ( $\geq 76$  years) were associated with a lower revision risk (HR=0.46, 95% CI 0.25 to 0.83,  $p=0.010$ ) compared to patients  $\leq 60$  years (Table 5). After risk adjusting, surgical approach was not selected for the final model.

When covariates were tested for multiplicative relations a significant interaction between age group and shell type was found ( $p=0.022$ ). Bearing category remained significant ( $p=0.048$ )

but age group and shell type as individual covariates no longer met the inclusion criteria for the model. This suggests that lower risk of revision in patients  $\geq 76$  years was associated with multi-hole shells and lower risk of revision in patients  $\leq 60$  was associated with solid-back shells (Table 6). In this model, CoC bearings were not associated with significantly higher revision, although this was marginal (HR=1.86, 95% CI 0.97 to 3.56, p=0.061).

Revision risk was independent of gender, ASA grade, stem characteristics, head size, neck offset, cement type, operator grade and consultant experience.

### ***Revision rates***

The overall five-year revision rate was 1.56% (95% CI 1.23 to 1.89) for the entire study population. In patients  $\leq 75$  years, five-year revision rates for solid-back shells were 1.21% (95% CI 0.67 to 1.76) compared with 2.07% (95% CI 1.52 to 2.62) for multi-holes (Table 7). Three-year revision rates for bearing and shell type indicate the use of a MoXLPE bearing with a solid-back shell may ultimately have the lowest revision rate, although there were no statistically significant differences across these small groups.

## **Discussion**

This retrospective cohort study provides the largest, in-depth analysis of a single brand combination of hybrid THRs. Significantly greater revision rates were associated with bearing surface material and shell type after risk adjustment. These findings identify modifiable parameters in the control of the operating surgeon. Other potentially modifiable factors, including surgical approach and femoral head size, were not found to significantly influence revision.

Whilst these data are the largest to date reporting a single brand combination analysis of hybrid THRs, we accept that there are limitations in its interpretation. The revision rates described in this study are limited to mid-term data only (the earliest implanted was 2003). The relative rates at which particular implants require revision may change with further follow-up and more informative data. In addition, the highly cross-linked PE in this system has only been used in considerable numbers since 2007, limiting comparisons across bearings. Revision is a hard end-point and may be considered a surrogate marker of implant failure, as other endpoints are unavailable. This does not take into account patients living with a painful hip, or those awaiting revision at the time of censoring (13). Furthermore, revision procedures may be missed by the NJR due to compliance and linkage issues, but these should affect all groups equally. The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. Information regarding duration and severity of symptoms, radiographic appearance and activity levels prior to and following the procedure were not available. However, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and time independence support the stability of estimates.

Highly cross-linked polyethylene has improved resistance to wear compared to standard PE, resulting in generation of fewer wear particles (14). A meta-analysis of ongoing clinical trials found XLPE liners exhibited reduced radiological wear and osteolysis at a mean follow-up of 5.1 years (1.8 to 9.0) compared to standard PE. Although there was no difference in revision rates between the types of PE, concerns regarding early failures attributable to brittleness of the XLPE were unfounded (15). A mid- to long-term implant survival analysis of almost 9000 primary procedures from the Mayo clinic using thirteen different cementless cup systems found improved survival (although not statistically significant) with XLPE liners compared to standard PE liners (16). This current study is the first to identify an implant survival benefit of XLPE liners within a single acetabular system, albeit using short- to mid-term data.

Ceramic-on-ceramic bearings have good mid- to long-term survival data (17). It is anticipated that a low wearing CoC bearing should provide adequate longevity for the young, active patient. However, there are concerns regarding higher risks of dislocation (18), fracture and squeaking (17). This current study has identified that MoXLP is currently (marginally) outperforming CoC in the Trident system. However, CoC and MoXLPE bearings may have equivalent survival in patients aged  $\leq 60$  years. CoC bearings may ultimately provide greater longevity in younger patients, but longer-term data is required.

The use of the multi-hole shell option allows supplementary screw fixation of the cup, rather than reliance on press-fit alone. The decision to use a multi-hole shell may be explained by: inadequate press-fit of the trial/solid shell; anatomical factors (e.g. wall defects) precluding the use of cemented cups or press-fit components without screw augmentation; or the operating surgeon's normal practice. From the data presented here, multi-hole shells are

associated with higher revision in younger patients, but possibly lower revision in older patients. Although we have no data on screw usage, it is assumed that a (more expensive) multi-hole shell would be used in conjunction with screws in the majority of cases, to supplement inadequate press-fit. This potentially poorer method of fixation, the reduced surface area for bony in-growth, or wear debris migrating through the holes, may contribute to the higher revision seen in these multi-hole shells in younger patients. Conversely, in older patients with poorer bone quality, reliance on press-fit alone may not be adequate in any patients, and supplementary fixation with screws may provide greater fixation. Of note, no difference in revision was found between PSL and Hemispherical shells.

Previous reports have shown that increasing age is associated with lower revision rates after cemented THR (10, 19). We found an interaction with shell type, which may explain the lower revision rates in older patients in this study. However, it is important to remember that patients  $\geq 76$  years have lower functional demands, and fewer patients requiring revision surgery will be fit enough in this age group, limiting the conclusions that can be drawn when patient reported functional and general health data are unavailable. Furthermore, 10-year patient survival following THR performed in older patients (aged  $\geq 80$  years) is less than 25% according to Norwegian Registry data (20). The literature reports no superiority of cementless over cemented cups at ten years (21) and, given costs are generally higher than cemented, we question the cost-effectiveness of the use of cementless cups in 3976 (25%) patients  $\geq 76$  years in this current analysis.

As expected, the overall revision presented here at five years 1.56% (95% CI 1.23 to 1.89) was similar to reports from the NJR 8<sup>th</sup> AR for 18 358 Exeter V40/Trident THRs (1.69%, 95% CI 1.39 to 2.07) (7). However, revision at five years when the commonest bearing

(CoC) was used in combination with a solid-back shell in patients  $\leq 75$  years was only 1.13% (95% CI 0.43 to 1.83). Although the follow-up time is shorter, the data presented here suggests that MoXLPE, in combination with a solid shell has even lower revision. Overall revision, as described in the analyses of brands alone in the NJR 8<sup>th</sup> Annual Report, is therefore skewed by longer follow-up data from poorer performing components (historical higher use of standard PE). Components that are now most commonly used in current practice (MoXLPE, CoC bearings) have lower revision rates than those reported by the NJR.

Increasing femoral head size is thought to contribute to lower dislocation (22) and revision (11). However, in this study there were no differences in revision rates across head sizes. Of note, surgical approach did not influence revision after adjustment for other factors. Although BMI appeared to have an influence on the model, with the degree of missing data it was felt that excluding this parameter was the most appropriate solution. Efforts to improve BMI recording to allow for appropriate adjustment in future explanatory analysis are required.

The commonest primary reason for revision was infection (27.0%); dislocation accounted for 25.5% of revisions. This study reports mid-term data: as expected, only a small number of implants (23.4%) were revised for aseptic loosening/lysis. Excluding dislocation, cup related failures (aseptic loosening/lysis, malalignment, dissociation of liner, and liner wear) were cited in 39.7% (56) of revisions, compared with 9.9% (14) for stems. Of note, previous concerns regarding high rates of mal-seating of the Trident ceramic liners (8 to 16.4% of all procedures) (23, 24) do not appear to translate into liner dissociation and subsequent revision procedures (3.5% of revisions were attributable to ceramic liner dissociations in this series).



In summary, there were significant differences in implant failure between bearing surface materials and acetabular shell fixation types, after adjustment for a range of covariates in a large cohort of single-brand hybrid THRs. In this study, standard polyethylene liners and multi-hole Trident shells were associated with significantly higher revision rates overall. Metal-on-highly-cross-linked polyethylene in a shell with no holes appears to be the best choice in patients  $\leq 75$  years, in short- to medium-term analysis of this popular hybrid brand combination. CoC bearings may have a role in the youngest patients. This study demonstrates that multiple factors can influence revision risk; registry data analyses may mislead if they fail to adjust for all relevant covariates when comparing across brands and types. For surgeons using hybrid THR, the findings presented may help guide their practice. Findings may also provide a useful reference for comparison with future analyses comparing implant types.

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### **Conflict of Interests Statement**

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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**Table 1.** Final covariates used in the event analyses

Category	Variable type	Covariate
Age	Ordinal	$\leq 60$ years, 61-75, $\geq 76$
Gender	Binary	Female, Male
ASA grade	Ordinal	Grade $\leq 2$ , Grade $\geq 3$
Body mass index	Ordinal	$< 30 \text{ kg/m}^2$ , $\geq 30 \text{ kg/m}^2$
Stem offset	Ordinal	35mm, 37.5mm, 44mm, 50mm
Stem taper	Ordinal	$\leq 2$ , $\geq 3$
Head size	Ordinal	28mm, 32mm, $\geq 36$ mm
Neck offset	Ordinal	Standard, 'Plus' head, 'Minus' head
Shell design	Nominal	Solid-back, Multi-/cluster-hole
Bearing	Nominal	Metal-on-standard polyethylene (PE) Metal-on-highly-cross-linked (XL) PE Ceramic-on-standard PE Ceramic-on-XLPE Ceramic-on-ceramic
Cement type	Nominal	Palacos high viscosity antibiotic impregnated, Simplex P antibiotic impregnated, Other
Surgical approach	Nominal	Posterior, Anterolateral, Other
Year of procedure	Continuous	2003 to 2010
Primary surgeon	Binary	Consultant, Other
Consultant Exeter/Trident volume	Ordinal	Low ( $\leq 50$ cases throughout study period), Medium (51-200), High ( $\geq 201$ )

ASA – American Society of Anaesthesiologists, kg – kilogram, m – metre, mm – millimetre

**Table 2.** Demographics of Exeter V40/Trident hybrid hip replacements (England and Wales, 2003-2010)

	<b>n=15 740</b>
<i>Age, mean years (SD, range)</i>	67.5(10.7, 15-102)
≤60, n (%)	3535 (22.5)
61-75	8229 (52.3)
≥76	3976 (25.3)
<i>Gender</i>	
Female	9573 (60.8)
Male	6167 (39.2)
<i>ASA grade</i>	
1/2	13 693 (87.0)
≥3	2047 (13.0)
<i>Body mass index, mean kg/m<sup>2</sup> (SD)</i>	28.4 (5.3)*
<30kg/m <sup>2</sup> , n (%)	4638 (29.5)
≥30kg/m <sup>2</sup>	2003 (12.7)
No data	9099 (57.8)
<i>Stem offset</i>	
35.5mm	1186 (7.5)
37.5mm	5135 (32.6)
44mm	8627 (54.8)
50mm	792 (5.0)
<i>Stem taper</i>	
≤2	14 255 (90.6)
≥3	1485 (9.4)
<i>Head size</i>	
28mm	4764 (30.3)
32mm	7153 (45.4)
≥36mm	3823 (24.3)
<i>Neck offset</i>	
Standard (0)	9986 (63.4)
Plus (+4mm to +8mm)	2534 (16.1)
Minus (-2.7mm to - 5mm)	3220 (20.5)
<i>Shell design</i>	
Solid back	5243 (33.3)
PSL	3882 (24.7)
Hemispherical	1361 (8.6)
Multi-hole	10 497 (66.7)
PSL	6934 (44.1)
Hemispherical	3563 (22.6)
<i>Bearing</i>	
Metal-on-standard polyethylene (PE)	4265 (27.1)
Metal-on-highly cross-linked (XL) PE	3829 (24.3)
Stainless steel-on-XLPE	1661 (10.6)
Cobalt-chrome-on-XLPE	2168 (13.8)
Ceramic-on-standard PE	354 (2.2)
Ceramic-on-XLPE	1148 (7.3)
Ceramic-on-ceramic	6144 (39.0)
<i>Cement</i>	
Palacos high viscosity antibiotic impregnated	8264 (52.5)
Simplex P antibiotic impregnated	5530 (35.1)
Other	1484 (9.4)
Missing	462 (2.9)
<i>Surgical approach</i>	
Posterior	10 620 (67.5)
Anterolateral	4662 (29.6)
Other	319 (2.0)
Missing data	139 (0.9)

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<i>Year of procedure</i>		
2003	74	(0.5)
2004	376	(2.4)
2005	1125	(7.1)
2006	1755	(11.1)
2007	2590	(16.5)
2008	2867	(18.2)
2009	3610	(22.9)
2010	3343	(21.2)
<i>Primary surgeon</i>		
Consultant	12 886	(81.9)
Other	2854	(18.1)
<i>Number of consultants (n)</i>	575	
<i>Consultant Exeter/Trident volume</i>		
Low ( $\leq 50$ cases over study period)	4593	(29.2)
Medium (51-200)	6969	(44.3)
High ( $\geq 201$ )	4178	(26.5)
<i>Number of surgical units (n)</i>	239	

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SD – standard deviation, \* - based on 6641 procedures

**Table 3.** Bearings used for Exeter v40/Trident hybrid hip replacements, by year (England and Wales, 2003-2010)

Year	Bearing				
	MoXLP	MoSP	CoSP	CoXLP	CoC
2003, n (%)	0 (0)	26 (35.1)	5 (6.8)	0 (0)	43 (58.1)
2004	1 (0.3)	140 (37.2)	28 (7.4)	0 (0)	207 (55.1)
2005	6 (0.5)	453 (40.3)	62 (5.5)	1 (0.1)	603 (53.6)
2006	25 (1.4)	785 (44.7)	88 (5.0)	10 (0.6)	847 (48.3)
2007	383 (14.8)	956 (36.9)	56 (2.2)	65 (2.5)	1130 (43.6)
2008	782 (27.3)	671 (23.4)	40 (1.4)	242 (8.4)	1132 (39.5)
2009	1292 (25.8)	666 (18.4)	45 (1.2)	425 (11.8)	1182 (32.7)
2010	1340 (40.1)	568 (17.0)	30 (0.9)	405 (12.1)	1000 (29.9)
<i>Total</i>	<i>3829 (24.3)</i>	<i>4265 (27.1)</i>	<i>354 (2.2)</i>	<i>1148 (7.3)</i>	<i>6144 (39.0)</i>

MoXLP – metal-on-cross-linked polyethylene, MoSP – metal-on-standard polyethylene,  
CoSP – ceramic-on-standard polyethylene, CoXLP – ceramic-on-cross-linked polyethylene,  
CoC – ceramic-on-ceramic

**Table 4.** Reasons recorded for revision following Exeter V40/Trident hybrid hip replacement (England and Wales, 2003-2010)

	<b>Revision (n=141)</b>
Infection, n (%)	<b>38 (27.0)</b>
Dislocation	<b>36 (25.5)</b>
All aseptic component loosening/lysis	<b>33 (23.4)</b>
<i>Stem only</i>	4 (2.8)
<i>Cup only</i>	23 (16.3)
<i>Both</i>	6 (4.3)
All malalignments	<b>18 (12.8)</b>
<i>Stem only</i>	3 (2.1)
<i>Cup only</i>	14 (9.9)
<i>Both</i>	1 (0.7)
Periprosthetic fracture	<b>17 (12.1)</b>
<i>Stem only</i>	13 (9.2)
<i>Cup only</i>	4 (2.8)
Dissociation of liner	<b>7 (5.0)</b>
All implant fractures	<b>6 (4.3)</b>
<i>Stem only</i>	4 (2.8)
<i>Cup only</i>	2 (1.4)
Unexplained pain	<b>8 (5.7)</b>
Liner wear	<b>5 (3.5)</b>
Other	<b>5 (3.5)</b>



**Table 5.** Independent predictors of revision following 15 740 Exeter/Trident hybrid hip replacements:  
simple and multivariable Cox regressions  
(England and Wales, 2003-2010)

Covariate	Simple analysis			Multivariable analysis		
	HR	95% CI	P value	HR	95% CI	P value
<i>Gender</i>						
Female	1					
Male	1.04	0.74-1.45	0.829			
<i>Age</i>						
Category			0.033			0.037
≤60 years	1			1		
61-75	0.79	0.54-1.14	0.201	0.75	0.50-1.11	0.148
≥76	0.50	0.30-0.84	0.009	0.46	0.25-0.83	0.010
<i>ASA grade</i>						
1/2	1					
≥3	1.08	0.66-1.77	0.766			
<i>Stem offset</i>						
Category			0.613			
35.5mm	0.73	0.34-1.59	0.429			
37.5mm	1.01	0.70-1.46	0.943			
44mm	1					
50mm	1.38	0.74-2.60	0.316			
<i>Stem taper</i>						
≤2	1					
≥3	0.63	0.32-1.24	0.180			
<i>Head size</i>						
Category			0.152			
28mm	1.28	0.89-1.84	0.176			
32mm	1					
≥36mm	0.82	0.51-1.33	0.421			
<i>Neck offset</i>						
Category			0.139			
Standard	1					
Plus	1.38	0.89-2.15	0.152			
Minus	1.41	0.95-2.10	0.085			
<i>Bearing</i>						
Category			0.050			0.035
Metal-on-XLPE	1			1		
Metal-on-standard PE	2.46	1.30-4.65	0.006	2.64	1.39-4.99	0.003
Ceramic-on-standard PE	3.51	1.37-9.00	0.009	3.07	1.18-8.00	0.022
Ceramic-on-XLPE	1.98	0.78-5.04	0.150	1.86	0.72-4.77	0.198
Ceramic-on-ceramic	2.29	1.23-4.26	0.009	1.93	1.00-3.69	0.049
<i>Shell</i>						
Solid back	1			1		
Multi-hole	1.54	1.06-2.24	0.024	1.70	1.16-2.48	0.006
<i>Cement</i>						
Category			0.169			
Palacos HV antibiotic	1					
Simplex P antibiotic	0.97	0.67-1.41	0.876			
Other	1.55	0.95-2.52	0.082			
<i>Surgical approach</i>						
Category			0.036			
Posterior	1					
Antero-lateral	1.53	1.09-2.15	0.015			
Other	0.51	0.07-3.63	0.497			
<i>Year of procedure</i>	1.06	0.94-1.19	0.341			
<i>Operator</i>						
Consultant	1					
Other	1.28	0.85-1.91	0.237			

*Consultant Exeter/Trident  
volume*

Category			0.273
Low ( $\leq 50$ )	1.14	0.71-1.83	0.597
Medium (51-200)	1.40	0.91-2.13	0.130
High ( $\geq 201$ )	1		

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HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists,  
XLPE – highly cross-linked polyethylene, PE – polyethylene

**Table 6.** Revision following 15 740 Exeter/Trident hybrid hip replacements: Multivariable Cox regressions with multiplicative interaction of age and shell type (England and Wales, 2003-2010)

Covariate	Multivariable analysis		
	HR	95% CI	P value
<i>Age</i>			
Category			0.330
≤60 years	1		
61-75	0.79	0.49-1.25	0.307
≥76	0.62	0.33-1.17	0.141
<i>Bearing</i>			
Category			0.048
Metal-on-XLPE	1		
Metal-on-standard PE	2.52	1.33-4.78	0.005
Ceramic-on-standard PE	2.99	1.50-7.78	0.025
Ceramic-on-XLPE	1.74	0.68-4.45	0.252
Ceramic-on-ceramic	1.86	0.97-3.56	0.061
<i>Shell</i>			
Solid back	1		
Multi-hole	1.37	0.91-2.07	0.135
<i>Age*shell</i>			
Category			0.022
≤60 years	1		
61-75	0.80	0.33-1.94	0.628
≥76	0.23	0.08-0.70	0.010

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, XLPE – highly cross-linked polyethylene, PE – polyethylene

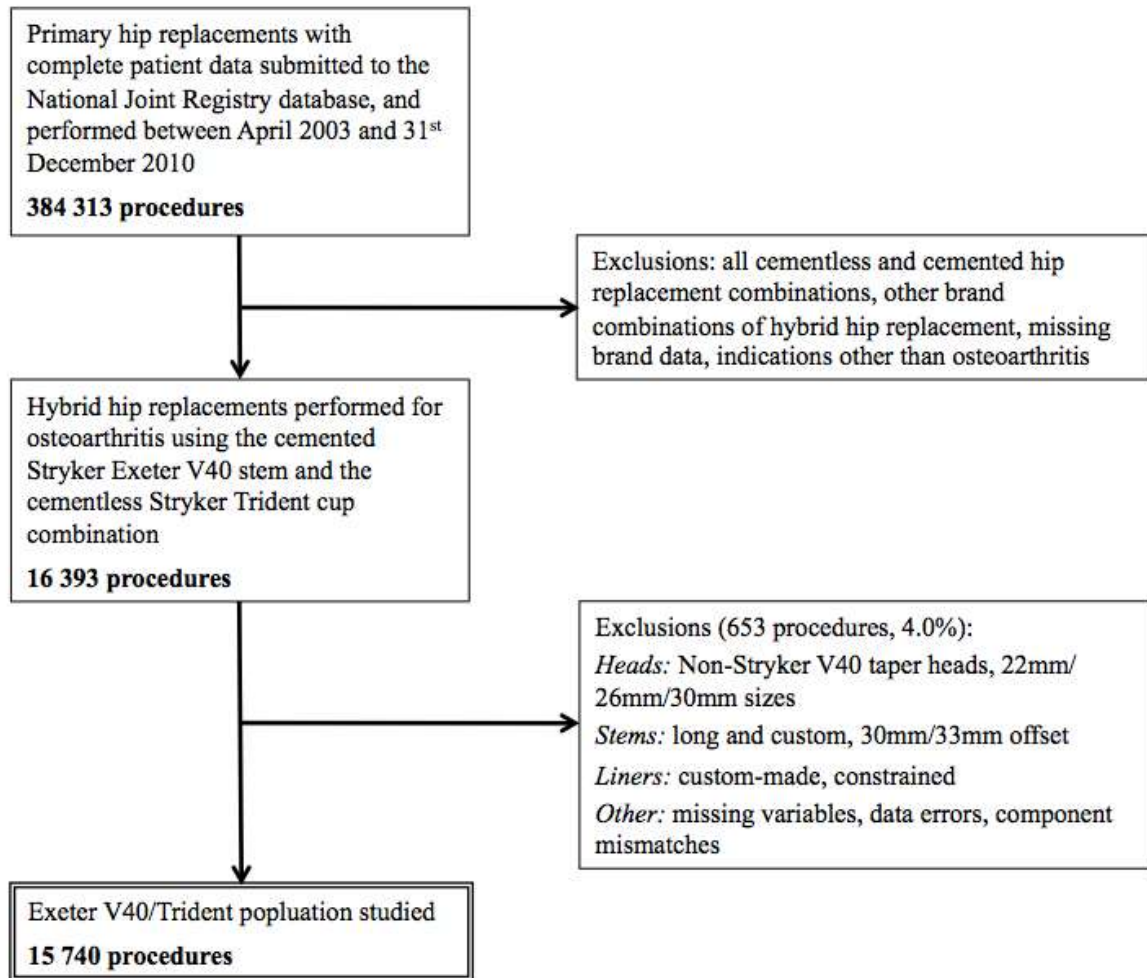
**Table 7.** Revision rates following Exeter/Trident hybrid hip replacement by bearing and shell type in patients  $\leq 75$  years (95% confidence intervals) (England and Wales, 2003-2010)

	Revision rates by bearing				Overall revision rates
	MoXLP	MoSP	CoXLP	CoC	
1-year					
All	0.33% (0.07-0.60)	0.73% (0.39-1.08)	0.65% (0.08-1.21)	0.54% (0.35-0.74)	0.57% (0.43-0.71)
Solid shell	0.24% (0.00-0.72)	0.79% (0.21-1.37)	- -	0.25% (0.03-0.46)	0.40% (0.20-0.59)
Multi-hole shell	0.36% (0.05-0.68)	0.70% (0.27-1.13)	0.67% (0.00-1.42)	0.73% (0.44-1.02)	0.67% (0.47-0.86)
3-year					
All	0.72% (0.26-1.18)	1.36% (0.87-1.86)	1.49% (0.10-2.87)	1.10% (0.79-1.41)	1.14% (0.92-1.37)
Solid shell	0.24% (0.00-0.72)	1.35% (0.55-2.16)	- -	0.42% (0.13-0.71)	0.64% (0.37-0.91)
Multi-hole shell	0.86% (0.28-1.44)	1.37% (0.74-2.00)	2.15% (0.00-4.51)	1.57% (1.08-2.06)	1.46% (1.13-1.79)
5-year					
All	- -	2.01% (1.25-2.78)	- -	1.66% (1.15-2.16)	1.74% (1.35-2.13)
Solid shell	- -	1.78% (0.63-2.92)	- -	1.13% (0.43-1.83)	1.21% (0.67-1.76)
Multi-hole shell	- -	2.17% (1.14-3.19)	- -	1.99% (1.30-2.67)	2.07% (1.52-2.62)
Total number					
All	2193	2476	937	5831	11 764
Solid shell	504	957	375	2202	4180
Multi-hole shell	1689	1519	562	3629	7584

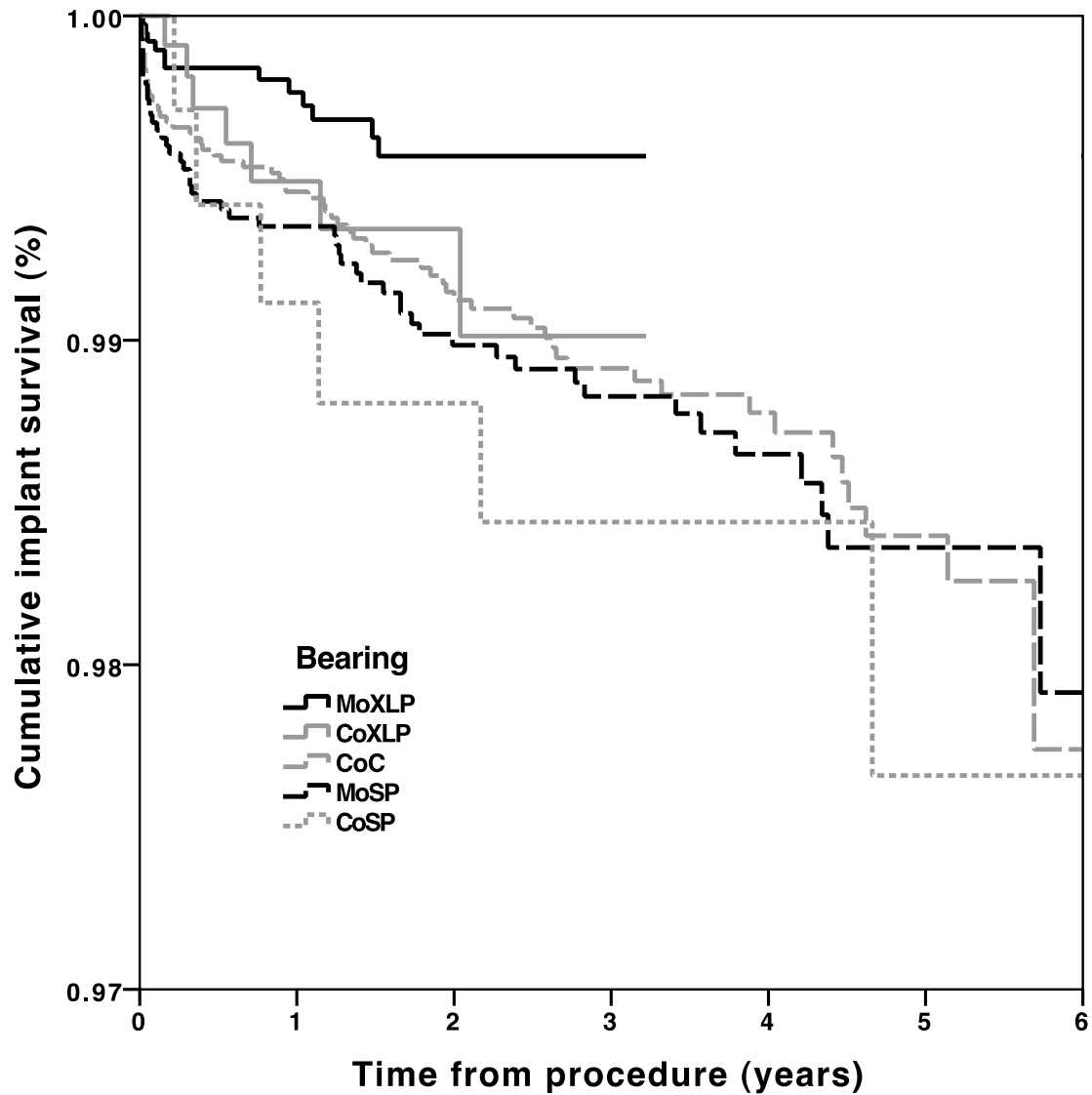
Inadequate numbers of CoSP for analysis.

For sub-analysis of data, where numbers were inadequate no figures are reported.

**Figure 1.** Flow chart describing the procedures included



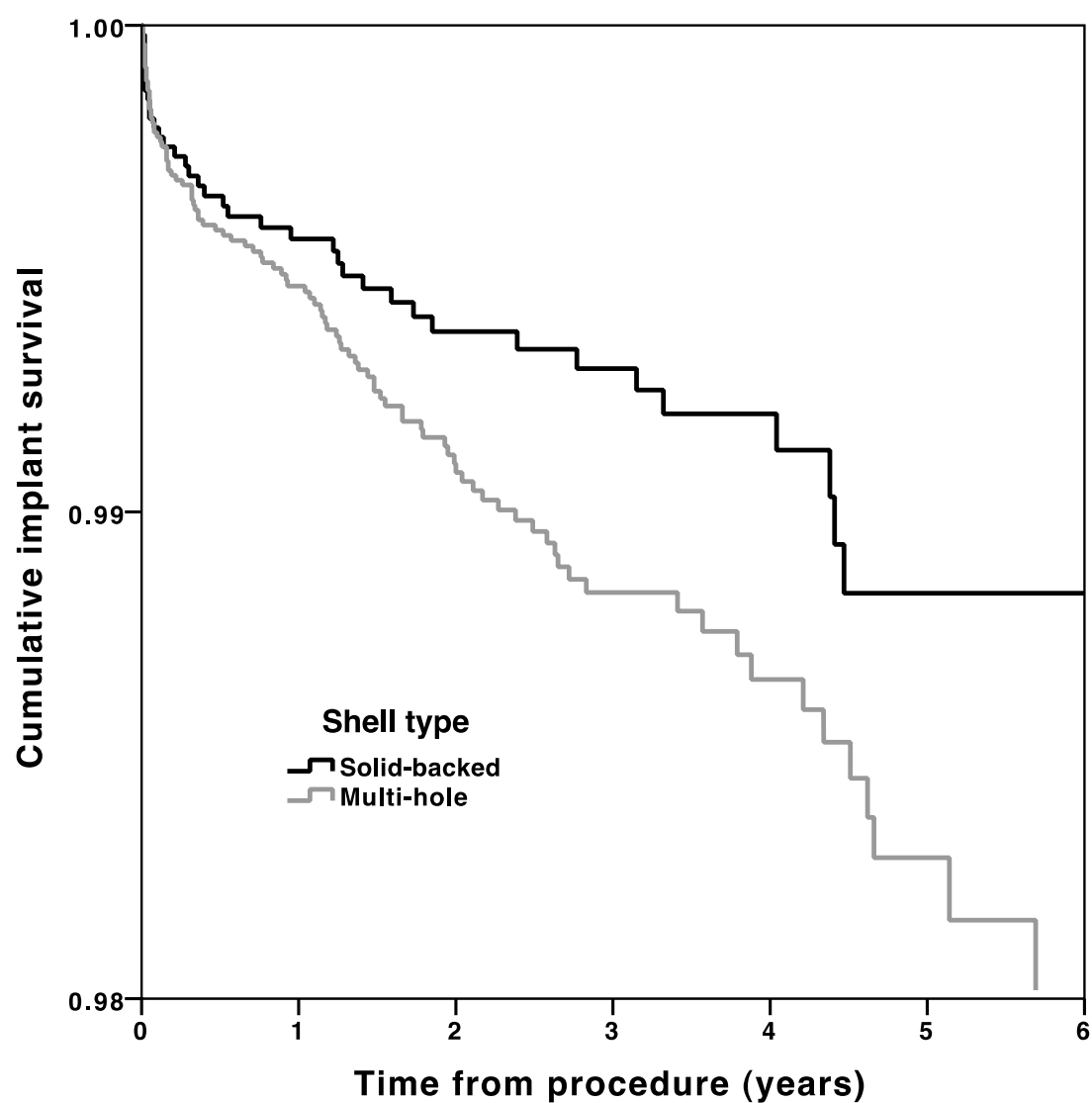
**Figure 2.** Kaplan Meier: unadjusted cumulative implant survival of Exeter V40/Trident by bearing (England and Wales, 2003-2010)



Log rank (Mantel-Cox)	MoXLP	MoSP	CoSP	CoXLP	CoC
MoXLP (p-value)	-	0.003	0.015	0.149	0.010
MoSP	0.003	-	0.368	0.521	0.706
CoSP	0.015	0.368	-	0.399	0.296
CoXLP	0.149	0.521	0.399	-	0.798
CoC	0.010	0.706	0.296	0.798	-

Life table showing numbers at risk in each year						
Cup design	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
MoXLP	3829	2452	1146	395	30	7
MoSP	4265	3618	2911	2196	1276	554
CoSP	354	320	274	232	175	91
CoXLP	1148	728	305	72	8	1
CoC	6144	5100	3885	2753	1637	814

**Figure 3.** Kaplan Meier: unadjusted cumulative implant survival of Exeter V40/Trident by shell type (England and Wales, 2003-2010)



Log rank (Mantel-Cox)	Solid	Multi-hole
Solid-back shell (p-value)	-	0.023
Multi-hole shell	0.023	-

Life table showing numbers at risk each year

Shell type	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Solid-back shell	5243	4187	3098	2413	1343	597
Multi-hole shell	10497	8031	5423	3235	1783	870

## Supplementary material

The reliability of the Cox model was explored by alternative stepwise procedures using the likelihood ratio test. Covariates found not to be statistically significant were excluded from the model, based on statistical entry ( $p < 0.05$ ) and rejection ( $p > 0.10$ ) criteria. The same covariates were fitted forward and reverse stepwise to ensure findings were not qualitatively affected in the final model, with any inconsistency reported. The final model was re-evaluated as a directly entered model (non-stepwise) to provide unconditional estimates, and was assessed by exploring 2-way interactions between covariates and for the constant proportionality over time assumption. In order to improve efficiency of the final models, where no differences were found within subcategories (e.g. shell geometry type) during preliminary modelling, these were combined. All models were fitted using SPSS version 19.0 (SPSS Inc, IBM Corporation, Armonk, New York).

On univariable analysis, age as a continuous covariate was a significant influence (HR=0.98, 95% CI 0.96 to 1.00,  $p=0.016$ ). We therefore created separate multivariable models to test age selection (as continuous or categorical data). As a continuous covariate, age did not affect selection within the model, nor the influence of the other significant covariates (multi-hole shell: HR=1.69, MoSP bearing: HR=2.65, CoSP: HR=3.15, CoXLP: HR=1.89, CoC: HR=1.94). The final model was therefore reported with age using categorical data.

High BMI ( $\geq 30 \text{ kg/m}^2$ ) was associated with an increased risk of revision compared to BMI  $< 30 \text{ kg/m}^2$  on univariable analysis ( $\geq 30 \text{ kg/m}^2$ : HR=2.03, 95% CI 1.15 to 3.58,  $p=0.015$ ). This inclusion of BMI in the preliminary multivariable modelling resulted in the loss of 58% of available procedures from the analysis, and while the HRs for individual bearings were not qualitatively affected by this, shell type and age were not selected within the model



(supplementary Table 1). This substantial data loss was accompanied by stepwise selection instability, and so BMI was therefore removed from the final analysis.

Tests for time-dependency of covariates were not statistically significant. Forward and reverse stepwise model construction led to the same final model.

**Supplementary Table 1.** Independent predictors of revision following 15 740 Exeter/Trident hybrid hip replacements, including body mass index data: simple and multivariable Cox regressions (England and Wales, 2003-2010)

Covariate	Simple analysis			Multivariable analysis*		
	HR	95% CI	P value	HR	95% CI	P value
<i>Gender</i>						
Female	1					
Male	1.04	0.74-1.45	0.829			
<i>Age</i>						
Category			0.033			
≤60	1					
61-75	0.79	0.54-1.14	0.201			
≥76	0.50	0.30-0.84	0.009			
<i>ASA grade</i>						
1/2	1					
≥3	1.08	0.66-1.77	0.766			
<i>Body mass index</i>						
<30kg/m <sup>2</sup>	1			1		
≥30kg/m <sup>2</sup>	2.03	1.15-3.58	0.015	2.00	1.13-3.54	0.017
<i>Stem offset</i>						
Category			0.613			
35.5mm	0.73	0.34-1.59	0.429			
37.5mm	1.01	0.70-1.46	0.943			
44mm	1					
50mm	1.38	0.74-2.60	0.316			
<i>Stem taper</i>						
≤2	1					
≥3	0.63	0.32-1.24	0.180			
<i>Head size</i>						
Category			0.152			
28mm	1.28	0.89-1.84	0.176			
32mm	1					
≥36mm	0.82	0.51-1.33	0.421			
<i>Neck offset</i>						
Category			0.139			
Standard	1					
Plus	1.38	0.89-2.15	0.152			
Minus	1.41	0.95-2.10	0.085			
<i>Bearing</i>						
Category			0.050			0.159
Metal-on-XLPE	1			1		
Metal-on-standard PE	2.46	1.30-4.65	0.006	1.97	0.71-5.45	0.194
Ceramic-on-standard PE	3.51	1.37-9.00	0.009	5.44	1.08-27.36	0.040
Ceramic-on-XLPE	1.98	0.78-5.04	0.150	3.16	1.02-9.81	0.046
Ceramic-on-ceramic	2.29	1.23-4.26	0.009	2.50	1.02-6.15	0.046
<i>Shell</i>						
Solid back	1					
Multi-hole	1.54	1.06-2.24	0.024			
<i>Cement</i>						
Category			0.169			
Palacos HV antibiotic	1					
Simplex P antibiotic	0.97	0.67-1.41	0.876			
Other	1.55	0.95-2.52	0.082			
<i>Surgical approach</i>						
Category			0.036			
Posterior	1					
Anterolateral	1.53	1.09-2.15	0.015			
Other	0.51	0.07-3.63	0.497			
<i>Year of procedure</i>	1.06	0.94-1.19	0.341			

<i>Operator</i>			
Consultant	1		
Other	1.28	0.85-1.91	0.237
<i>Consultant Exeter/Trident volume</i>			
Category			0.273
Low ( $\leq 50$ )	1.14	0.71-1.83	0.597
Medium (51-200)	1.40	0.91-2.13	0.130
High ( $\geq 201$ )	1		
<hr/> HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, XLPE – highly cross-linked polyethylene, PE – polyethylene, *based on 6637 procedures with body mass index data			